UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

February 17, 2015

Dr. Anne LeHuray
2308 Mount Vernon Avenue
Suite 134
Arlington, VA 22301

Re: Freedom of Information Request Number EPA-HQ-2015-003290

Dear Dr. LeHuray:

This letter is in response to your request dated January 15, 2015, under the Freedom of Information Act (FOIA). You are requesting access to and copies of all nominations and public comments received in response to (1) the January 28, 2014, Federal Register Notice titled "Request for Nominations of Experts to Augment the Science Advisory Board Chemical Assessment Advisory Committee for the Review of the EPA's Draft Toxocological Review of Benzo[a]pyrene," and (2) the document titled "Invitation for Public Comment on the List of Candidates for the EPA Science Advisory Board Chemical Assessment Committee Augmented for Benzo[a]pyrene Review" dated September 10, 2014, and posted on the EPA's website on September 11, 2014.

The Science Advisory Board (SAB) has identified two records responsive to your request. Of these documents, none were withheld in accordance with Exemption 5 under 5 U.S.C. §522 (b)(5), which allows an agency to withhold from disclosure inter-agency memoranda, e-mails, or letters of the deliberative process and none were withheld under Exemption 6 of the FOIA, 5 U.S.C. §552 (b)(6) which contain information (e-mail addresses and phone numbers and home addresses) that would represent and unwarranted invasion of privacy. Please find enclosed the requested information.

If you believe that the delivery of this FOIA is a denial of your request, you may appeal in writing to the National Freedom of Information Officer at:

Records, FOIA, and Privacy Branch
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
(2822T) Washington, D.C. 20460
Email: hq.foia@epa.gov

Please note that correspondence mailed only through the United States Postal Service may be delivered to the address above. If you want to deliver your appeal in person, via courier service, or via overnight delivery service, you must address your correspondence to 1301 Constitution Avenue, N.W., Room 64161, Washington, D.C. 20001.

Your appeal must be submitted no later than 30 calendar days from the date of this letter. The appeal letter should include the request number listed above. The Agency will not consider appeals received after the 30 calendar-day limit. For the quickest possible handling, the appeal letter and its envelope should be marked "Freedom of Information Act Appeal."

Sincerely,

Thomas H. Brennan
Deputy Director, Science Advisory Board

Enclosure

Pavement Coatings Technology Council

WWW.PAVEMENTCOUNCIL.ORG

October 2, 2014

Dr. Diana Wong, Designated Federal Officer
U.S. Environmental Protection Agency
Science Advisory Board Staff Office

wong.diana-M@epa.gov

Dear Dr. Wong,

Subject: Invitation for Public Comment on the List of Candidates for the EPA Science Advisory Board Chemical Assessment Advisory Committee Augmented for Benzo[a]pyrene Review (List of Candidates), September 10, 2014

On behalf of the Pavement Coatings Technology Council (PCTC), thank you for the opportunity to comment on the subject List of Candidates posted to the Environmental Protection Agency (EPA) Science Advisory Board (SAB) web site. That 72 distinguished scientists are willing to participate as members of the Benzo[a]pyrene (BaP) augmented Chemical Assessment Advisory Committee (CAAC) panel speaks to the importance of the BaP assessment. The task the BaP panel will be asked to undertake will differ in many ways from previous reviews of Integrated Risk Information System (IRIS) assessments. Thus, the focus of our comments is not on recommending individual candidates, but rather on the importance of identifying candidates with "the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the general charge" to effectively undertake the BaP review.

THE SAB BAP PANEL MAY BE THE FIRST IRIS PEER REVIEW OF A SUBSTANCE WITH A SUBSTANTIAL BODY OF HUMAN EXPOSURE DATA FROM THE MEDICAL LITERATURE

EPA is in the process of improving its IRIS assessment process, as recommended by National Academy of Science panels. One of the IRIS enhancements is increased transparency and stakeholder involvement early in the process. The BaP assessment is one of the last IRIS cases proceeding without benefit of the early transparency enhancements, and provides a case study in why process changes were needed. The draft BaP assessment was subject to both internal EPA review and subsequent intra-agency review prior to release as a public review draft. In all these drafts, the hazard assessment was based on many incorrectly cited and anecdotal reports of adverse effects of human exposures to materials containing high PAH concentrations, such as coal tar and coal tar derived substances while discounting or ignoring the substantial body of literature concerning medicinal uses of coal tar and coal tar derived pharmaceuticals. Public

2308 Mount Vernon Avenue, Suite 134
Alexandria Virginia 22301

Phone: +1 (703) 299-8470
Fax: +1 (703) 842-8850
alehuray@pavementcouncil.org

SAB for instituting this measure, which will not only promote consistency but will also foster a broader awareness within the SAB and among CAAC members of overarching issues provoked by the BaP review. If EPA must choose among the candidate members for assignment to the augmented CAAC BaP review panel, we urge EPA to primarily consider those candidate members with experience with pharmacological data, species differences and dermal toxicology.

2. Several of the listed candidates served as members of the SAB's peer review panel for the IRIS program's *Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures (External Review Draft)* document. PCTC commends EPA and the SAB for encouraging continuity with the RPF panel, as BaP is used in EPA's RPF approach as the index compound for the PAHs. One of the recommendations of the RPF panel was that EPA fund testing of representative PAH-containing mixtures by the National Toxicology Program (NTP) with a view to future improvements in PAH risk assessments. Thus, participants in the RPF panel are well aware of many of the issues that they will be asked to review in peer reviewing the BaP assessment. Once again, if EPA must choose among candidates who also participated in the RPF panel, we again urge that the choice be made keeping in mind some of the broad philosophical questions that pertain to the draft BaP assessment.
3. The draft hazard assessment relied on many incorrectly cited and anecdotal reports of adverse effects associated with exposure to PAH-containing substances. Public comments challenged the draft hazard assessment. The BaP panel will be asked to review the hazard assessment. To ensure appropriate consideration of associations between exposures to BaP- and BaP equivalent-containing compounds and reports of adverse effects, as well as studies of patients published in the medical/pharmacological literature, the panel should include several epidemiologists. The List of Candidates includes a number of well qualified epidemiologists. Preparation of the public comments on the draft hazard assessment was a time consuming exercise involving review of the materials cited in the draft as well as uncited materials. A well conducted SAB panel review is not likely to require less effort. For this reason, we recommend that EPA consider including three or four epidemiologists on the panel.
4. Classification of coal tar as GRASE for use in over-the-counter skin medications by FDA and similar international government agencies means there are millions of people worldwide who intentionally slather themselves every day with lotions, creams and ointments that contain high concentrations of BaP and BaP equivalents (i.e., other PAHs). Including scientists with an understanding of FDA drug approval and classification processes could prove crucial to the BaP panel's peer review. Two of the candidates are identified as current or former researchers at FDA's National Center for Toxicological

scientists with considerable expertise on a sometimes very narrow issue associated with chemical hazard and risk assessment. We hope that industry scientists have not been discouraged by the drumbeat of anti-industry rhetoric from some in the activist community. In the case of BaP and the PAHs, many industry scientists have the requisite expertise and experience to peer review EPA's IRIS assessment without any possible conflict of interest - the universe of companies that use or make products containing BaP and the PAHs is readily identifiable. To promote balance of points of view as well as to punctuate the principle that science should be evaluated on its merits, not sources of funding or anti-industry bias, we urge the SAB to select the sole industry-affiliated scientist as a member of the BaP peer review panel.

Thank you for your consideration. Please feel free to contact me at alehuray@pavementcouncil.org or at (703) 299-8470.

Yours truly,

Anne P. LeHuray, Ph.D.
Executive Director

EDF
ENVIRONMENTAL DEFENSE FUND
Finding the ways that work

Environmental Defense Fund

Comments on
List of Candidates to augment the Science Advisory Board (SAB) Chemical Assessment Advisory Committee (CAAC) peer review of EPA's draft IRIS Toxicological Review of Benzo[a]pyrene

Submitted: October 10, 2014

Environmental Defense Fund (EDF) appreciates the opportunity to comment on the List of Candidates for the Science Advisory Board (SAB)'s Chemical Assessment Advisory Committee (CAAC) peer review panel for EPA's draft IRIS Toxicological Review of benzo[a]pyrene. This panel will evaluate the scientific and technical validity of the draft assessment.

As a subcommittee of the chartered SAB, the CAAC is subject to the Federal Advisory Committee Act (FACA), the Ethics in Government Act of 1978, and all SAB Office policies regarding avoidance of conflicts of interest and appearances of a lack of impartiality. These policies are reflected in consolidated guidance found in the Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board, which states that "[if] a conflict exists between a panel candidate's private financial interests and activities and public responsibilities as a panel member, or even if there is the appearance of partiality, as defined by federal ethics regulations, the SAB Staff will, as a rule, seek to obtain the needed expertise from another individual" (pages 9-10). Similarly, according to the posted Invitation for Public Comment, criteria used to evaluate candidates for this augmented panel include "absence of financial conflicts of interest" and "absence of appearance of a lack of impartiality" (page 1).

EDF has reviewed the list of candidates for this peer review panel and is concerned about a potential financial conflict of interest or an appearance of a lack of impartiality, or both, with respect to two of the candidates. EDF wishes to emphasize that our comments are not intended in any way to challenge the scientific and technical expertise or impugn the integrity of this proposed panel member.

Dr. Robert Skoglund

Dr. Skoglund is a Senior Laboratory Manager at the 3M Company. The 3M Company, which employs Dr. Skoglund, owned and/or conducted industrial activities at sites that are now brownfield sites contaminated with benzo[a]pyrene, the subject of the assessment to be

1875 Connecticut Avenue, NW
Washington, DC 20009
T 202 387 3500
F 202 234 6049
edf.org
New York, NY / Austin, TX / Bentonville, AR / Boston, MA / Boulder, CO / Raleigh, NC
Sacramento, CA / San Francisco, CA / Washington, DC / Beijing, China / La Paz, Mexico

reviewed by this CAAC panel.[1] These sites became contaminated with benzo[a]pyrene due, in part, to activities by the 3M Company (abrasives factory, machine shop, maintenance shop, storage and fabrication activities).[2,3]

Furthermore, the EPA's Toxics Release Inventory (TRI) database lists 3M as producing one or more of a group of 10 polycyclic aromatic compounds that includes benzo[a]pyrene,[4] at its site in Decatur, Alabama.[5]

Given Dr. Skoglund's employer's financial interest in benzo[a]pyrene and his responsibility, as stated in the biosketch for him posted by the SAB, for "assessment and communication of the hazards and risks of materials important to 3M," EDF believes that Dr. Skoglund would lack the appearance of impartiality and may have a financial conflict of interest with respect to his proposed participation in a review of the IRIS assessment of benzo[a]pyrene. Therefore, Dr. Skoglund's participation in a review of the benzo[a]pyrene IRIS assessment may be a violation of government ethics requirements.

Dr. Martha Moore

Dr. Martha Moore is a senior manager at Environ. This year, scientists from Environ, the RJ Reynolds Tobacco Company and British American Tobacco Company reported on work they have jointly conducted, presenting a poster at the 2014 Society of Toxicology annual meeting. The project involves the development of an inhalation physiologically based pharmacokinetic (PBPK) model for benzo[a]pyrene.[6] This project was funded by both the RJ Reynolds Tobacco Company and British American Tobacco. As benzo[a]pyrene is a compound found in cigarettes, both of these companies stand to have a financial interest in the outcome of any assessment of hazards or risks of benzo[a]pyrene, including the IRIS assessment.

Given this work conducted by the company that employs Dr. Moore, EDF requests that SAB staff further investigate whether she has been involved in any manner in these or other Environ projects funded by either of these tobacco companies or otherwise focused on benzo[a]pyrene,

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[1] http://cfpub.epa.gov/bf_factsheets/gfs/index.cfm?xpg_id=7409&display_type=HTML.
[2] http://www.sppa.com/wp-content/uploads/2009/10/DRAFT-10-2-Cleanup-Grant-3M-Parcel-5.pdf.
[3] http://sppa.com/wp-content/uploads/2009/10/DRAFT-10-2-Cleanup-Grant-3M-Parcel-4.pdf.
[4] See TRI data at: http://iaspub.epa.gov/triexplorer/release_fac?p_view=USFA&trilib=TRIQ1&sort=_VIEW_&sort_fmt=1&state=All+states&county=All+counties&zipcode=&epa_region=&chemical=N590&industry=325&year=2013&tab_rpt=1&FLD=RELLBY&FLD=TSFDSP.
[5] See TRI data at: http://oaspub.epa.gov/enviro/tri_formr_partone_v2.get_details?rpt_year=2013&fac_id=35602MCMPNSTATE&ban_flag=Y.
[6] See poster board number 106 on p. 137 of the 2014 SOT meeting program, available at http://www.toxicology.org/AI/Pub/Prog/2014Program.pdf. The poster itself is available on the British American Tobacco website at http://www.bat-science.com/groupms/sites/BAT_9GVJXS.nsf/vwPagesWebLive/DO9NNDJX/$FILE/SOT_2014_CM.pdf?openelement.

as we believe such involvement could constitute a conflict of interest and at the very least a lack of the appearance of impartiality.

In addition, EDF would like to bring to the SAB staff's attention that, if it has not done so already, searches need to be conducted using information from EPA's CDR and TRI databases. Specifically:

- Numerous companies have reported the recent production or import of benzo[a]pyrene to EPA under its Chemical Data Reporting (CDR) rule. In the CDR database, seven companies reported manufacturing benzo[a]pyrene. However, all but one of the companies claimed their identity as confidential business information (CBI), the exception being Ocean Investments Corp.
- In the TRI database, benzo[a]pyrene is a member of a group of "polycyclic aromatic compounds", which does not allow the public to discern which companies are releasing benzo[a]pyrene specifically.

Because of the CBI, we have been unable to further investigate. In order to conduct a complete conflict of interest review, the CDR and TRI information need to be obtained by SAB Staff. Staff will need to obtain the names of the other companies reporting under the CDR and additional detailed information relating to polycyclic aromatic compounds reported to EPA under the TRI. That information should then be used to conduct searches using those names and prospective peer review panelists to determine if any of the candidates have financial relationships with any companies reporting manufacture or release of benzo[a]pyrene.

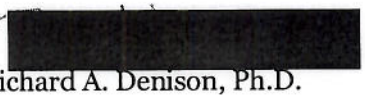
EDF encourages the SAB staff to evaluate peer review panel candidates through the following internet searches:

- Name of each company identified through CDR and TRI databases and "candidate name"
- Name of each company identified through CDR and TRI databases and "candidate's employer name"

We urge the SAB Staff to take the information provided in these comments into account as it finalizes the membership of this augmented CAAC panel.

Please let us know if you have any questions or wish to discuss this matter further. We appreciate the opportunity to comment and look forward to the timely completion of the review of this EPA IRIS assessment.

Respectfully submitted,



Richard A. Denison, Ph.D.
Senior Scientist

Lindsay A. McCormick
Research Analyst

Widecast List of Nominees for the SAB Chemical Assessment Advisory Committee Augmented for Benzo[a]pyrene Review

Person	Organization	City	State	Special Expertise Needed	Who Referred	Comment
Anderson, Henry	Wisconsin Division of Public Health	Madison	WI	Epidemiology, Occupational Medicine	Person is a CAAC member	
Bartell,Scott	University of California - Irvine	Irvine	CA	Epidemiology; Quantitative risk assessment	Person is a CAAC member	
Bruckner, James V	University of Georgia	Athens	GA	Toxicology, Risk Assessment	Person is a CAAC member	
Cory-Slechta,Deborah	University of Rochester	Rochester	NY	Neurotoxicity	Person is a CAAC member	
Foster, William Michael	Duke University Medical Center	Durham	NC	Inhalation Toxicology	Person is a CAAC member	
Goeden,Helen	Minnesota Department of Health	St. Paul	MN	Quantitative risk assessment	Person is a CAAC member	
Harris, Cynthia M	Florida A & M University	Tallahassee	FL	Toxicology, Risk Assessment	Person is a CAAC member	
Hauser, Russ	Harvard University	Boston	MA	Epidemiology	Person is a CAAC member	
Hays,Sean	Summit Toxicology	Allenspark	CO	Toxicokinetics	Person is a CAAC member	
Klaunig,James E.	Indiana University	Bloomington	IN	Cancer biology	Person is a CAAC member	
Lash, Lawrence	Wayne State University	Detroit	MI	Drug metabolism and transport, renal toxicology	Person is a CAAC member	
Lichtveld,Maureen	Tulane University	New Orleans	LA	Cancer biology	Person is a CAAC member	
Li,Abby A.	Exponent Incorporated	San Francisco	CA	Neurotoxicity; Quantitative risk assessment	Person is a CAAC member	
Morandi, Maria	Independent Consultant	Houston	TX	Pulmonary Physiology, Industrial Hygiene	Person is a CAAC member	
Persky, Victoria	University of Illinois at Chicago	Chicago	IL	Epidemiology	Person is a CAAC member	
Philbert,Martin	University of Michigan	Ann Arbor	MI	Neurotoxicity	Person is a CAAC member	

Widecast List of Nominees for the SAB Chemical Assessment Advisory Committee Augmented for Benzo[a]pyrene Review

Person	Organization	City	State	Special Expertise Needed	Who Referred	Comment
Bunge, Annette	Colorado School of Mine	Golden	CO	Dermal Toxicokinetics	self	Interested
Burbacher, Thomas	University of Washington	Seattle	WA	Neurodevelopmental	DFO	Not Interested
Burchiel, Scott	University of New Mexico	Albuquerque	NM	Immunotoxicology of PAH, BaP	DFO, self	Interested
Catalano, Paul	Harvard School of Public Health	Cambridge	MA	Biostatistics	DFO	Not Interested
Cavalieri, Ercole	University of Nebraska Medical Center	Omaha	NE	BaP carcinogenesis	DFO	Interested
Chou, Karen	Michigan State University	East Lansing	MI	Reproductive Toxicology	DFO	Interested
Costa, Lucio	University of Washington	Seattle	WA	Neurodevelopmental	DFO	Not Interested
Cranmer, Joan	University of Arkansas	Little Rock	AR	Neurodevelopmental	DFO	Not Interested
Crowell, Susan	Pacific Northwest National Laboratory	Richland	WA	Toxicokinetics	Dr. Richard Corley, Pacific Northwest National Laboratory	Interested
Curtis, Haris	National Cancer Institute	Bethesda	MD	BaP expert	DFO	Not interested
Di Giulio, Richard	Duke University	Durham	NC	Developmental toxicity, Reproductive toxicity, Genotoxicity	Marcia Lawson, SOT	Interested
DiGiovanni, John	University of Texas	Smithville	TX	BaP Expert	DFO, Self	Interested
Emond,Claude	University of Montreal	Montréal	QC	Toxicokinetics	Self	Interested
Faustman, Elaine	University of Washington	Seattle	WA	Reproductive and Developmental Toxicology	Person is a Chartered Board Member	Interested

Widecast List of Nominees for the SAB Chemical Assessment Advisory Committee Augmented for Benzo[a]pyrene Review

Person	Organization	City	State	Special Expertise Needed	Who Referred	Comment
Kissel, John	University of Washington	Seattle	Washington	Dermal toxicokinetics	DFO, self	Interested
Langlois,Peter	Texas Department of State Health Services	Austin	TX	Epidemiology; Reproductive toxicity	Self	Interested
Levin, Ed	Duke University	Durham	NC	Neurodevelopmental	Dr. Thomas Burbacher	interested
Luderer, Ulrike	University of California at Irvine	Irvine	CA	Reproductive & Developmental Toxicology	DFO	Not Interested
Marsit, Carmen	Darmouth	Hanover	NH	Neurodevelopmental	Self	Interested
McDonald, Jacob	Lovelace Respiratory Research Institute	Albuquerque	NM	Inhalation Toxicology	Self	Interested
McElroy,Anne	Stony Brook University	Stony Brook	NY	Genotoxicity	Dr. ADRIA ELSKUS, U.S. Geological Survey	Not interested
McIntyre, Barry	NIEHS	Research Triangle Park	NC	Reproductive & Developmental Toxicology	Self	Interested
Melnick,Ronald	Ron Melnick Consulting, LLC	North Logan	UT	Genotoxicity; Cancer biology; Toxicokinetics; Quantitative risk assessment	Dr. Richard Denison, Environmental Defense Fund	Interested
Moon, Hojin	California State University	Long Beach	CA	Biostatistics	DFO	Not Interested
Moore,Martha	Environ	Little Rock	AR	Genotoxicity	Self	Interested
Morris, John	University of Connecticut	Storrs	CT	Inhalation Toxicology	DFO	Not Interested
Moorthy,Bhagavatula	Baylor College of Medicine	Houston	TX	Developmental toxicity; Cancer biology; Quantitative risk assessment	Ms. Marcia Lawson, Society of Toxicology	Interested

Widecast List of Nominees for the SAB Chemical Assessment Advisory Committee Augmented for Benzo[a]pyrene Review

Person	Organization	City	State	Special Expertise Needed	Who Referred	Comment
Rider,Cynthia	National Institute of Environmental Health Sciences	Durham	NC	Developmental toxicity; Neurotoxicity; Reproductive toxicity; Immunotoxicity; Cancer biology; Toxicokinetics; Quantitative risk assessment	Ms Marcia Lawson, Society of Toxicology	Interested
Riviere, James	Kansas State University	Manhattan	KS	Dermal toxicity	SAB staff Office	Not interested
Ryan, Louise	Harvard School of Public Health	Boston	MA	Biostatistics	DFO	Not interested, moved to Australia
Sahmel,Jennifer	Cardno ChemRisk	Boulder	CO	Dermal toxicity; Quantitative risk assessment	Dr. Sherilyn Gross, Cardno ChemRisk	Interested
Schantz, Susan	University of Illinois	Urbana	IL	Neurodevelopmental	Dr. Thomas Burbacher	Not Interested
Schlesinger, Richard	Pace University	New York	NY	Inhalation Toxicology	DFO	Interested
Simon,Ted	University of Georgia	Winston	GA	Risk assessment	Self	Interested
Slotkin, Theodore	Duke University	Durham	NC	Neurodevelopmental	DFO	Not Interested
Spencer, Peter	Oregon Health & Science University	Portland	OR	Neurodevelopmental	Self	Interested
van den Hurk,Peter	Clemson University	Clemson	SC	Developmental toxicity; Reproductive toxicity; Quantitative risk assessment	Marcia Lawson, SOT	Interested
Vorhees, Charles	University of Cincinnatti	Cincinnati	OH	Neurodevelopmental	Dr. Thomas Burbacher	Interested